Amendments to and listing of the Claims:

Please cancel claims 2-5, 7, 8, 14, 25, and 28,-35, without prejudice, and amend claims 1, 9, 11-13, and 24-27 as set forth in the following listing of the claims, which replaces all prior versions, and listings of claims in the application:

1. (Currently Amended) A composition in the form of an aqueous solution or suspension for nasal or ocular delivery of a therapeutic agent across a mucosal surface having a viscosity of 150ep or less at 25% and into systemic circulation, the composition comprising (i) chitosan, a salt thereof or a derivative thereof that has been formed by bonding of acyl or alkyl groups with the hydroxyl groups of the chitosan or a salt of [[a]]the derivative-thereof, (ii) a polyol-phosphate or sugar-phosphate salt, (iii) a plasticizer, and (iv) a therapeutic agent intended for systemic action.

2.-5. (Canceled)

- (Previously Presented) The composition according to claim 1, wherein the plasticizer is triethyl citrate.
- (Currently Amended) The composition as claimed in claim 1, wherein the
 chitosan, the salt or the derivative thereof or the salt of [[a]]the derivative-thereof has a
 molecular weight of 4000 Dalton or greater.
- (Currently Amended) The composition according to claim 7, wherein the
 chitosan, the salt or the derivative thereof or the salt of [[a]]the derivative thereof, has a
 molecular weight of from 50,000 to 300,000 Dalton.
- (Currently Amended) The composition according to claim 1, comprising chitosan base or a chitosan derivative that has been formed by bonding of acyl-or alkyl groups with the hydroxyl groups of the chitosan or a nitrate, phosphate, sulphate, citrate, hydrochloride, glutamate, lactate or acetate salt of chitosan.
- 10. (Previously Presented) The composition according to claim 1, wherein the chitosan has a degree of deacetylation of 40 % or greater.

U.S. Patent Application 10/598,212 Reply to Office Action of January 8, 2010

- 11. (Currently Amended) The composition according to claim [[12]]10, wherein the degree of deacetylation is from 70 to 90 %.
- 12. (Currently Amended) The composition according to claim 1, comprising from 0.25 to 3.0 % w/v of the chitosan, [[a]]the salt or [[a]]the derivative thereof or [[a]]the salt of [[a]]the derivative thereof expressed as chitosan base.
- 13. (Currently Amended) The composition according to claim 12 comprising from 0.45 to 1.5 % w/v of the chitosan, [[a]]the salt or [[a]]the derivative thereof or [[a]]the salt of [[a]]the derivative thereof expressed as chitosan base.

14. (Canceled)

- 15. (Previously Presented) The composition according to claim 1, wherein the polyol-phosphate salt is β-glycerophosphate disodium.
- 16. (Previously Presented) The composition according to claim 1, wherein the polyol-phosphate or sugar-phosphate salt is present in an amount of from 0.25 to 3.0 % w/v.
- 17. (Previously Presented) The composition according to claim 16, wherein the polyol-phosphate or sugar-phosphate salt is present in an amount of from 0.75 to 2.0 % w/v.
- 18. (Previously Presented) The composition according to claim 1, comprising from 0.05 to 5.0 % w/v of the plasticizer.
- 19. (Previously Presented) The composition as claimed in claim 18, comprising from 0.2 to 1.0 % w/v of the plasticizer.
- (Previously Presented) The composition according to claim 1, additionally comprising ascorbic acid.
- (Previously Presented) The composition according to claim 20, comprising from 0.01 to 0.2 % w/v ascorbic acid.

- 22. (Previously Presented) The composition according to claim 1, wherein the therapeutic agent is a polar drug, a polypeptide, a gene or a gene construct.
- 23. (Previously Presented) The composition according to claim 22, wherein the therapeutic agent is insulin, calcitonin, leuprolide, luteinising hormone releasing hormone, growth hormone or a growth hormone releasing factor, naratriptan, sumatriptan, zolmitriptan, rizatriptan, eletriptan, frovatriptan, alnitidan, avitriptan, almotriptan, apomorphine, sildenafil, alprostadil, diamorphine, hydromorphone, buprenorphine, fentanyl, oxycodone, codeine, morphine or morphine-6-glucuronide.
- 24. (Withdrawn-Currently Amended) A drug delivery device suitable for delivery of a composition via one or more of the nasal vaginal, rectal, oral mucosal, ophthalmic or ocular routes or a dose cartridge for use with such a device loaded with a composition as defined in claim 1.
- 25. (Withdrawn-Currently Amended) A process for the preparation of the composition as defined in claim 1, which process comprises mixing a solution comprising chitosan or a salt or derivative thereof or a salt of a-the_derivative-thereof with a solution comprising a polyol-phosphate or sugar-phosphate salt.
- 26. (Withdrawn-Currently Amended) The use of the combination of A process for transporting a systemically acting therapeutic agent across a nasal or ocular mucosal surface of an animal, the process comprising administering to the animal's nasal or ocular mucosal surface a composition in the form of an aqueous solution or suspension comprising chitosan or a salt thereof or derivative thereof that has been formed by bonding of acyl or alkyl groups with the hydroxyl groups of the chitosan or the a salt of a the derivative thereof, a polyol-phosphate or sugar-phosphate salt, and a plasticizer in the manufacture of a medicament for use in the transport of a and the systemically-acting therapeutic agent-across a mucosal surface in an animal.
- 27. (Withdrawn-Currently Amended) The use of the combination of A process for nasal or ocular delivery of a systemically acting therapeutic agent to an animal, the process comprising nasally or ocularly delivering to the animal a composition in the form of an aqueous solution or suspension comprising chitosan or a salt thereof or derivative thereof that has been formed by bonding of acyl or alkyl groups with the hydroxyl groups of the chitosan or

U.S. Patent Application 10/598,212 Reply to Office Action of January 8, 2010

the <u>a</u> salt of <u>a-the</u> derivative thereof, a polyol-phosphate or sugar-phosphate salt, and a plasticizer in the manufacture of a medicament for nasal vaginal, rectal, oral mucosal, ophthalmic or ocular delivery and the systemically acting therapeutic agent.

28.-35. (Canceled)